In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-1357V

UNPUBLISHED

ARETTA DIANE JAMES, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: March 15, 2021 Special Processing Unit (SPU); Dismissal; Onset; Insufficient Evidence; Influenza (Flu) Vaccine; Guillain- Barré Syndrome (GBS)

Emily Beth Ashe, Anapol Weiss, Philadelphia, PA, for Petitioner.

Alexa Roggenkamp, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION[1]

On September 6, 2019, Aretta Diane James filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"), alleging (under the Vaccine Act Table) that she suffered Guillain-Barré syndrome ("GBS") caused-in-fact by the influenza ('flu") vaccine she received on October 19, 2016. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

For the reasons set forth below, I hereby DENY entitlement in this case. Petitioner has not preponderantly established that she has met the definition for a Table GBS, or that the timeframe in which her GBS occurred (four months post-vaccination) was

[1] Because this unpublished Decision contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

medically appropriate for purposes of establishing vaccine causation under a non-Table version of the same claim.

I. Relevant Procedural History

In her petition and affidavit, Ms. James alleged that she suffered symptoms of her GBS less than a month after vaccination. Petition at ¶ 4; Exhibit 2 at ¶ 10. She also attributed the difficulties she experienced when attempting to undergo an electrocardiogram ("EKG") on December 23, 2016, approximately 64 days after vaccination, to her later diagnosed GBS. Petition at ¶ 5; Exhibit 2 at ¶ 11. On February 6, 2020, she indicated she had filed all medical records required by the Vaccine Act. *See* Statement of Completion, ECF No. 21.

On August 7, 2020, Respondent filed Rule 4(c) Report, opposing compensation in this case. ECF No. 27. Asserting that the onset of Petitioner's GBS in fact occurred 17 to 18 weeks after vaccination, Respondent argued that this "temporal relationship is well outside of the Table timeframe, and quite frankly outside of any reasonable attribution of causation to the flu vaccine." *Id.* at 10.[3] Accordingly, and after my own review of the record (at that time) suggested that the first symptom of Petitioner's GBS did not occur until mid-February 2017 at the earliest, or approximately four months after vaccination, I issued an order to show cause on December 16, 2020, why the Table claim should not be dismissed for failure to meet the onset period set by the Table. ECF No. 29. I also informed Petitioner that this timeframe is not medically appropriate for non-Table causation, and allowed her 60 days to provide additional evidence to establish the onset she described. *Id.* at 4.

As a response to the order to show cause, Petitioner filed only one page of a record from a medical portal, mywvuchart.com, regarding a November 8, 2016 visit to address a complaint of a cough and chest congestion. Exhibit 11, filed twice on Jan. 26 and 28, 2021, ECF Nos. 31, 33. The record indicates that Petitioner's fibromyalgia was also addressed. Petitioner reported that she "[w]as seen at rheumo[tology] in [M]organstown [and] was suggested to start on tramadol and trazadone." *Id.* The record also contains a list of Petitioner's vaccines, including the flu vaccine alleged as casual in this case. *Id.* However, the full record from this visit cannot be found in the medical records previously filed. *See* Exhibit 8 (UWV Medical Center records). And the partial record filed does not contain identifying information such as Petitioner's name. Exhibit 11. Additionally, Petitioner provided no order to show cause response regarding the information in and relevant of the record or reason why the full record was not provided or previously filed.

[3] Referencing evidence of EMG/NCV studies performed two years prior to vaccination (*id.* at 10 n.2), Respondent also argued that Petitioner may have suffered from chronic inflammatory demyelinating polyneuropathy ("CIDP") that likely pre-dated receipt of the flu vaccine (*id.* at 11). However, for purposes of the present analysis, I will focus on GBS, since it is the alleged injury, and since record evidence does support the diagnosis's accuracy.

The matter is now ripe for adjudication.

II. Applicable Legal Standards

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on her claim if the vaccinee for whom she seeks compensation has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the Table). Section 11(c)(1)(C)(i). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). If petitioner establishes that the vaccinee has suffered a "Table Injury," causation is presumed.

If, however, the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, petitioner must prove that the administered vaccine caused injury to receive Program compensation on behalf of the vaccinee. Section 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove her claim by preponderant evidence. Section 13(a)(1)(A). This standard is "one of . . . simple preponderance, or 'more probable than not' causation." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing *Hellebrand v. Sec'y of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993). The Federal Circuit has held that to establish an off-Table injury, petitioners must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Circuit Court has indicated that petitioners "must show 'a medical theory causally connecting the vaccination and the injury'" to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface*, 165 F.3d at 1352-53 (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" *Id.* The Federal Circuit subsequently reiterated these requirements in its *Althen* decision. *See* 418 F.3d at 1278. *Althen* requires a petitioner

> to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of *Althen* must be satisfied. *Id.*

Finding a petitioner is entitled to compensation must not be "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." Section 13(a)(1). Further, contemporaneous medical records are presumed to be accurate and complete in their recording of all relevant information as to petitioner's medical issues. *Cucuras v. Sec'y of Health & Human Servs.*, 993, F.2d 1525, 1528 (Fed. Cir. 1993). Testimony offered after the events in questions is considered less reliable than contemporaneous reports because the need for accurate explanation of symptoms is more immediate. *Reusser v. Sec'y of Health & Human Servs.*, 28 Fed. Cl. 516, 523 (1993).

III. Analysis

To meet the definition of a Table GBS following receipt of the seasonal flu vaccine, a petitioner must establish that the first symptom or manifestation of onset of her GBS occurred between three to 42 days after vaccination. 42 C.F.R. § 100.3(a) XIV.D. (2017). Even for a causation-in-fact claim, a petitioner must establish "a proximate temporal relationship between vaccination and injury." *Althen,* 418 F.3d at 1278 (third *Althen* prong).

A. Evidence Regarding Onset in Petitioner's Medical Records

1. Petitioner's Prior Condition

The medical records from Ms. James's neurologist show that, prior to vaccination, she suffered from diabetes, advanced osteoarthritis, and chronic back pain, for which she had multiple surgeries and other treatment efforts. Exhibit 5 at 123 (summary from February 23, 2016 visit). It was noted that she was taking Neurontin[4] for her pain. *Id.* When treated for numbness in her left arm on March 8, 2016, Petitioner was assessed as

[4] Neurontin is a "trademark for preparations of gabapentin." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ("DORLAND'S") at 1268 (32th ed. 2012).

having degenerative disc disease and peripheral neuropathy. *Id.* at 121. She was administered a Tramodol[5] injection, prescribed an oral narcotic for her pain, and instructed to continue taking Neurontin. *Id.*

On May 8 and 9, 2016, Petitioner visited the emergency room ("ER") complaining of three days of pain all over, characterized as generalized myalgias. Exhibit 3 at 840. Petitioner's histories of diabetes, chronic back pain, and rheumatoid arthritis were noted in the ER medical records. *Id.* She recounted her ER visits when seen by her neurologist on May 10, 2016. Exhibit 5 at 114. Mild bilateral neuropathies in Petitioner's wrists were noted on results from an upper extremities NCV/EMG performed in May 26, 2016. Exhibit 10 at 465.

When seen by her oncologist on June 10, 2016, Petitioner reported an "increase chronic fatigue, left ankle swelling, diffuse bone pain, pain in [her] hands, arms, legs, and intermittent left lower quadrant abdominal discomfort with constipation." Exhibit 8 at 5. Approximately one week later, she visited an urgent care clinic for a sore throat and weakness and swelling in her hands and feet. Exhibit 4 at 32. She described tingling and bilateral pain in her arms and hands but indicated that was her normal baseline. *Id.* The next day, the urgent care clinic provider instructed Petitioner to go to the ER due to her high glucose levels. Exhibit 3 at 648. When discharged from the ER, her diagnoses included diabetic neuropathy and rheumatoid arthritis. *Id.*

2. Petitioner's Condition Post-Vaccination

There are no entries in the medical records from the date of vaccination until later in February 2017 that would establish GBS symptoms. The partial record from a November 8, 2016 visit, which was produced in December 2020, indicates only that Petitioner at the time complained of a cough and chest congestion, was suffering from an URI and fibromyalgia, and had been recently seen by a rheumatologist and started on tramadol and trazadone. Exhibit 11. Furthermore, one page printed from a medical portal in August 2019 is clearly incomplete; this record does not even contain Petitioner's name. *Id.*

Medical records regarding a stress test performed on December 23, 2016 (65 days after vaccination) reveal that Petitioner had difficulty completing a treadmill stress test due to right leg weakness. Exhibit 3 at 528. However, this limitation is consistent with her earlier back pain and generalized myalgias. Exhibit 3 at 528. For example, when seen for

[5] Tramadol hydrochloride is "an opioid analgesic used for the treatment of moderate to moderately severe pain." DORLAND'S at 1950.

her back pain in 2015, Petitioner reported continued pain down her right leg. At that time, she was using a cane to walk. Exhibit 5 at 250.

According to the medical records, Petitioner did not complain of symptoms which could arguably be attributed to her GBS until February 22, 2017, when seen at the ER for facial dropping and weakness in her extremities which she said had started the previous night, February 21. Exhibit 4 at 10. Reporting that her weakness was more severe on her right side, Petitioner mentioned her earlier episode of Bell's palsy when seventeen years old. She did not mention the flu vaccine she received in October 2016, however, or the earlier symptoms that she now claims to have suffered in November 2016.

When seen by her neurologist the next day, Petitioner again indicated her symptoms began on February 21, 2017, described in this record as "two days ago" and "on Tuesday." Exhibit 5 at 109. The fact that she received a "recent flu vaccine", but no exposure to chemicals is noted in this medical record. Neither Petitioner nor her neurologist, however, indicated at this time that there might be any causal relationship between her illness and this vaccine. Exhibit 5 at 109. Petitioner's neurologist determined she should be admitted to the hospital. *Id.*

In the history provided at the hospital, Petitioner's husband recalled that she had suffered from a fever and chills two to three weeks earlier. Exhibit 3 at 95. Petitioner reported some nausea and difficulty swallowing. *Id.* In the medical record from an assessment performed the next day, on February 24, 2017, Petitioner's symptoms are described as beginning one to one and a half weeks earlier and progressively worsening. *Id.* at 99.

B. Petitioner's Allegations Regarding Onset

Petitioner claims that she had no history of neurological disorders prior to vaccination other than Bell's palsy, plus peripheral neuropathy she experienced when 17 years old. Petition at ¶ 2; Exhibit 2 at ¶ 3. However, the record in this case shows that she suffered from diabetic neuropathy and carpal tunnel syndrome as well as generalized myalgias, chronic back pain, rheumatoid arthritis, and advanced osteoarthritis.

Additionally, Petitioner maintains that less than 30 days after receiving the flu vaccine on October 19, 2016, she suffered "from muscle pain, difficulty swallowing, fatigue, shortness of breath, tingling in her feet, arms, and fingers, and weakness in her extremities and face." Petition at ¶ 4; Exhibit 2 at ¶ 10. However, these described symptoms mirror those Petitioner reported at visits prior to vaccination, in May and June 2016. In June, she characterized these symptoms as her normal baseline. Furthermore, there are no entries in the medical records from 30 days after vaccination which support

Petitioner's assertion of even these symptoms, certainly no novel symptoms which could be attributed to her later GBS.

Throughout the medical records, Petitioner herself identified the onset of her GBS as mid-February 2017 or later. She mentioned her receipt of the flu vaccine only once, and there is nothing to suggest Petitioner or her treating physicians linked the GBS symptoms she exhibited to the October 2016 vaccination. The medical records contain no information which substantiates Petitioner's claim of symptoms within 30 days of vaccination.

C. Timing of the Onset of Petitioner's GBS

Reviewing the entire record in this case, I find that the onset of Petitioner's GBS occurred, *at the earliest*, in mid-February 2017, approximately four months after vaccination. Any symptoms Petitioner experienced before that time were consistent with symptoms she had experienced for years prior to vaccination and cannot be attributed to her GBS. Medical records information provided closer in time to vaccination by Petitioner affirms this timing.

This duration between vaccination and onset is well outside the 3-42-day period for a Table claim. It also is too great to establish the proximate temporal relationship required to satisfy the third *Althen* prong under a causation-in-fact standard, as established in numerous prior Program decisions. Claims alleging GBS after the flu vaccine have not succeeded when onset occurred more than six to eight weeks after vaccination. *See generally Chinea v. Sec'y of Health & Human Servs.,* No. 15-0095V, 2019 WL 1873322, at *29 (Fed. Cl. Spec. Mstr. Mar. 15, 2019) (citing *Barone v. Sec'y of Health & Human Servs*., No. 11-0707V, 2014 WL 6834557, at *13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (eight weeks is the longest reasonable timeframe for a flu/GBS injury)).

I and other special masters have denied entitlement when onset occurred more than three months after vaccination. *See Williams v. Sec'y of Health & Human servs.,* No. 19-1177V, 2021 WL 815921, at *5 (Fed. Cl. Spec. Mstr. Jan.19, 2021) (finding an onset of more than three months after vaccination not medically appropriate for GBS); *Aguayo v. Sec'y of Health & Human Servs.*, No. 12-563V, 2013 WL 441013, at *3 (Fed. Cl. Spec. Mstr. Jan. 15, 2013) (rejecting a latency of three- and one-half months for GBS); Corder v. Sec'y of Health & Human Servs., No. 08-228V, 2011 WL 2469736, at *27-29 (Fed. Cl. Spec. Mstr. May 31, 2011) (rejecting a four-month onset for GBS). Four months is definitely too long to support a non-Table version of Petitioner's claim.

IV. Conclusion

To date, and despite ample opportunity, Petitioner has failed to file preponderant evidence to establish a 30-day onset, as she alleges. Furthermore, I find that the onset of Petitioner's GBS occurred in a time frame that does not met the GBS Table definition or the proximate temporal relationship required for causation.

Petitioner was informed that failure to provide preponderant evidence that the onset of her GBS occurred in a medically appropriate time frame would be treated as either a failure to prosecute this claim or as an inability to provide supporting documentation for this claim. Accordingly, this case is DISMISSED for failure to prosecute. The clerk shall enter judgment accordingly.[6]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[6] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties' joint filing of notice renouncing the right to seek review.